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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,126	09/09/2003	Jean-Francois Bouquet	P06155US02/BAS	9209

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/657,126	Applicant(s) BOUQUET ET-AL.	
	Examiner Robert A. Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 14 and 20-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/194,025.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12-18-2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 9-18-2006 is acknowledged. The traversal is on the ground(s) that:

- No showing has been made that an undue burden would be placed on the Examiner if the entire application was examined.
- The search of Group I would inherently require examination of the cells in groups II and IV.
- The relation among groups I, II and IV are indicated by their being classified in the same class.
- The species election is traversed in view of MPEP 803, which states an election is inappropriate when the generic claim includes sufficiently few species that a search and examination of all species would not impose a serious burden on the examination. In the present the number of anti-apoptotic proteins to be search is low and are all interrelated as they share a similar function.

This is not found persuasive because:

- The examination of the various groups would not be coextensive in scope and therefore which constitutes a serious burden.
- The search of Group I would not result in a complete search of the inventions of Groups II and IV as group II is drawn to cells having anti-apoptotic gene whereas the cells of group I are limited to cells having the bcl-2 gene. Group IV has the

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additional limitation of having to be infected by a virus that is not commensurate in scope with containing the SV40T+t gene.

- Differing classifications was not the basis on which the restriction was made (see page 4 of the restriction requirement).
- It should be noted that a species election *per se* was not required of Applicant (see page 3 of the restriction requirement). Moreover, contrary to Applicant's assertion, the number of apoptotic proteins encompassed by the instant claims is not small. Claim 11 is drawn to **any** apoptotic gene.

Consequently, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-33 are pending. Claims 1-10, 14 and 20-33 are withdrawn from consideration. Claims 11-13 and 15-19 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 12-18-2003 has been considered. An initialed copy is attached hereto.

Claim Objections

Claims 11-12 and 15-17 are objected to as they are drawn in part to non-elected inventions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13 and 15-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,255,108. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to an avian cell line which are immortalized, but untransformed, comprising in their genome an anti-apoptotic bcl-2 gene and optionally the SV40 T+t gene. Said cell lines can be obtained from fibroblasts.

Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11, 15-17 and 19 of copending Application No. 11/031,417. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim sets are drawn to an avian cell line which are immortalized, but untransformed, comprising in their genome the SV40 T+t gene. Said cell lines can be obtained from avian tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evan (WO 93/20200 – IDS filed on 12-18-03) and Givol et al. (Cell Growth & Differentiation, 1994, Vol. 5, pages 419-429).

The instant claims are drawn to avian cells (cell line) that are immortalized, but untransformed, comprising an anti-apoptotic bcl-2 gene and optionally the SV40 T+t gene (under

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the control of the MTI promoter). Said cell lines can be obtained from avian tissues generally, or fibroblasts or epithelial cells specifically.

Evan discloses cells and cell lines comprising a bcl-2 gene wherein said gene is inserted into a vector (see page 19, line 30 to page 20, line 2 and page 20, lines 28-29). Evan further discloses that said gene can be episomal or integrated (see page 20, lines 25-26) and that said vector can be used with host cells from any multicellular organism (see page 20, line 18 and page 24, line 30 to page 25, line 1)) and that said host cells should be immortalized (see page 24, lines 25-27).

Evan differs from the instant invention in that he doesn't explicitly disclose the host cells as being obtained from avian tissues generally, or fibroblasts or epithelial cells specifically or that said cells contain the SV40 T+t gene under the control of the MTI promoter (as required by claims 15 and 16).

Givol et al. disclose chicken embryo fibroblasts containing a retroviral vector encoding bcl-2 (see abstract).

Consequently, it would have been obvious for one of ordinary skill in the art at the time the invention was made to utilize chicken embryo fibroblasts as the host cells for the vector disclosed by Evan as their use constitutes an obvious variant of the disclosed invention.

One would have had a reasonable expectation of success as Evan discloses any cell from a multicellular organism can be used in his system and Givol et al. have demonstrated that chicken embryo fibroblasts can be used to express a vector based bcl-2 gene.

With regard to claims 15 and 16, the SV40 T+t gene is commonly used in the art to immortalize cells. Moreover, the MTI promoter is a commonly used promoter. Consequently,

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their use would have been obvious to the skilled artisan when they immortalized the host cells as disclosed by Evan.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Robert A. Zeman". The signature is stylized with a large, looped initial "R" and a long, sweeping underline.

ROBERT A. ZEMAN
PRIMARY EXAMINER

December 6, 2006